RESEARCH REVIEW BOARD INC.

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Research Review Board Inc. (RRB)

Protocol Deviations & Violations / Unanticipated Problems Reporting System

Federal Regulation 21CFR 56.108(b)(1) requires the RRB to "follow written procedures for ensuring prompt reporting to the IRB …of…any unanticipated problems involving risks to human subjects or others…"

RRB provides a Protocol Deviations & Violations/Unanticipated Problems Reporting Form.

Please report occurrences within 10 days of becoming aware of them.

Use the Protocol Deviations & Violations/Unanticipated Problems Reporting Form to report the following:

- **Unanticipated Problems** which in the opinion of the investigator may adversely affect the rights, safety or welfare of the subjects, or which significantly impact the integrity of research data.

  Unanticipated problems are issues that do not fit the usual definition of an Adverse Event, but which may, in the opinion of the Investigator, involve risk to the subject, affect others in the research study, or significantly impact the integrity of research data. For example, report occurrences of breaches of confidentiality, destruction of study records, or unaccounted for study drug.

- **Unplanned Protocol Deviations/Violations** that have already occurred, that may adversely affect the rights, safety or welfare of subjects or the integrity of the research, AND for which you did not seek RRB pre-approval. Sites must utilize the attached RRB report form or a form which contains all the same information required in the RRB report form.

- **Deviations necessary to eliminate apparent immediate hazards to the human subjects** should be reported within 10 days on the attached Protocol Deviations & Violations/Unanticipated Problems Reporting Form. **Note: Planned Protocol Deviations** that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to the RRB for review and approval **prior to implementation** except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR 46.103 (b)(4); (FDA 21 CFR 56.108(a)(4); ICH 3.3.7].

General notes on reporting Unanticipated Problems and Protocol Deviations/Violations

- The reporting requirements for RRB may differ from the reporting requirements for the Sponsor.

- Please note that unnecessarily reporting events or problems that do not potentially affect the rights, welfare or safety of subjects in the study may impair the Board's ability to review and respond in a timely manner to actual situations where subject rights, welfare, or safety are threatened.